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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/142,043	12/01/98	MOSSAKOWSKA	D 88362/104

FOLEY & LARDNER
3000 K STREET N W
SUITE 500
WASHINGTON DC 20007-5109

HM12/0111

EXAMINER

KAUFMAN, C

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 01/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/142,043	Applicant(s) MOSSAKOWSKA ET AL.	
Examiner Claire M. Kaufman	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 10/26 has been entered.

Response to Arguments

5 The objection of claims 37, 43, 48, 51 for reciting both the actual amino acid sequence and SEQ ID NO is withdrawn. While the SEQ ID NO is required, it is Applicants' choice as to whether the actual sequence be also present or not. However, due to potential printer error of reproducing the amino acid sequence, Applicants might choose to recite only the SEQ ID NO in the claims.

10 The rejection of claims 54-56 under 35 USC 101, is withdrawn in view of the amendment to the claim.

 The rejection of claims 54-56 under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claim.

15 The rejection of claims 53-56 under 35 USC 112, first paragraph, written description, is withdrawn in view of Applicants' arguments and what is well known in the art.

Sequence Requirement

 According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. Claim 54 recites amino acid sequences, but must instead refer to appropriate SEQ ID NO.

Specification

25 The specification remains objected to for reasons of record set forth in the previous Office action (paper #13, see section 2a and b).

 Appropriate correction is required.

Claim Objections

Claim 39 is objected to because of the following informalities: at end of line 2, a second "at" is needed for clarification ("residue at at least one of ..."); in claim 39, end of line 3, "and" should be --or--; in claim 47, line 4 "poly peptide" should be one word; and in claim 48, last line, because "a host polypeptide" is unclear in terms of which host, --the-- or --said-- host polypeptide should be used. Appropriate correction is required.

Double Patenting

Claims 37, 51 and 57 remain rejected under the judicially created doctrine of double patenting over claims 2 and 10 of U. S. Patent No. 5,833,989 for the reasons or record set forth in the previous Office action (paper #13).

Applicants argue that the Examiner has not set forth the obviousness of the instant claims over the patented claims. The argument has been fully considered, but is not persuasive. On page 4 of paper #11 where the rejection was originally set forth, there is a complete explanation of obviousness. Because the claims of the instant application use the open language of "having", which is synonymous with "comprising", the instantly claimed polypeptide comprises 6-23 amino acids, but is not limited to have 23 or fewer amino acids. Therefore, patent claims read on the claims of the instant application and render the instant claims obvious.

Claim Rejections - 35 USC § 112

Claims 37-57 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action (paper #13).

Applicants argue that the examiner has provided no support for doubting the enablement of the full scope of the claims, and that not undue experimentation but only routine design choices are necessary in the instant case. The argument has been fully considered, but is not persuasive. In paper #11, section 5a, there is a full discussion of why the claims are not commensurate in scope with the disclosure. For example, the instant claims are not limited to polypeptides 23 amino acids or fewer, but encompass polypeptides that comprise at least amino acids 6-11 or 11-20 of SEQ ID NO:1. The specification shows only that a SRC3-derived polypeptide consisting of amino acids 154-186 displays anti-complement activity. Which

polypeptides comprising at least amino acids 6-11 or 11-20 of SEQ ID NO:1 but not at least SEQ ID NO:1, 4, 5, 7 or 8, have the disclosed function is unpredictable. The claims are extremely broad. There is little in the way of direction to allow the skilled artisan to make and use the claimed polypeptides commensurate in scope with the instant claims without undue experimentation because the structural limitation in the claims is very small so as to provide little in the way of structural requirement for the polypeptide, and there is a lack of examples and guidance in the specification and prior art about what polypeptides besides those consisting of SEQ ID NO:1, 4, 5, 7 or 8 would function as expected based on the information in the specification. By providing methods of making the myriad of polypeptides encompassed by the claims, Applicants have provided an invitation to experiment without a reasonable expectation of successfully making a representative number of polypeptides encompassed by the claims that the skilled artisan could use.

Applicants argue that the Federal Circuit Court considered the "intertwined issues of enablement and utility" and cites MPEP 2164.04. The argument has been fully considered, but is not persuasive. First, utility and enablement are separate rejections and the instant claims have not been rejected under lack of utility, which is distinguished from **scope** of enablement of how to make and use. Certainly there are species encompassed by the instant claims that have the asserted utility, therefore a rejection under 35 USC 101 as lacking utility has not been made. However, the specification does not enable the **full** scope of the claims. Second, in the cited section of the MPEP it is stated that "...doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation." The missing information is discussed in the preceding paragraph and the Office action originally stating the rejection.

Applicants argue that the example on page 22 of the specification contains the fragments of SEQ ID NO:1 set forth in the claims; and, therefore, have shown that the sequences are functional and the claims are enabled. The argument has been fully considered, but is not persuasive. The example shows that E1 (SEQ ID NO:4) showed anti-complement activity, and does not provide support for function of the great breadth of polypeptides encompassed by the claims.

The rejection of claims 37-57 under 35 USC 112, second paragraph, are maintained for the reasons of record set forth in the previous Office action (paper #13) in section 4.

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Claim Rejections - 35 USC § 102

Claims 37, 39 and 51-57 remain rejected under 35 U.S.C. 102(b) as being anticipated by Fearon et al. for the reasons of record set forth in the previous Office action (paper#13).

Applicants argue that there is no showing that the sequence or size recitations of the claims are disclosed by Fearon. The argument has been fully considered, but is not persuasive. Fearon discloses human CR1. SCR3 is a portion thereof (see page 17, lines 5-30 of the instant specification). Therefor the sequence is disclosed by Fearon. The claims are not limited to a specific size polypeptide since the term "having" used in the claims is open.

15

Claim Rejections - 35 USC § 103

Claims 48-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fearon et al. in view of Capon et al. for the reasons set forth in the previous Office action in paper #13.

Applicants argue that Capon et al. does not rectify the deficiencies in Fearon et al. The argument has been fully considered, but is not persuasive. For the reasons provided above in the preceding 102 section, Fearon does not have deficiencies with respect to teaching what is claimed.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

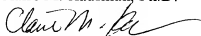
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

- 10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If

- 15 applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

- 20 Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

January 9, 2001